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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,707	06/30/2006	Artemis G. Hatzigeorgiou	UPN00027-100	1574

34136 7590 08/18/2009

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EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,707	HATZIGEORGIOU ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) *1-11 and 23-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-23-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the communication filed 5-4-09.

Claims 1-26 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group II, claims 12-22, in the reply filed on 5-4-09 is acknowledged. The traversal is on the ground(s) that Groups II, IV, and V should be joined as incorporating the computer algorithm described in claims 12-22. Applicant also argues that the restriction requirement should be withdrawn because the analysis employed is improper, according to Applicant, because PCT Rule 13.2 was cited in the requirement and applies only when the claims recite alternative forms of chemical compounds. This is not found persuasive for several reasons. Applicant argues that claims that are drawn to a method of predicting potential regulatory sequences (e.g. micro RNA sequences and corresponding MRE sequences in the mRNA) entitle an examination of all sequences that would potentially be identified in any genomic sequences of any organism. Applicant also argues that claims that are drawn to a method of predicting potential regulatory sequences entitle an examination of methods of using such sequences for target gene inhibition. Applicant also argues that a method of inhibiting gene expression in some way shares a common technical feature with a method of using an algorithm to predict the existence of potential molecules that might exist. Contrary to Applicant's assertions, the drafting of claims that utilize an algorithm or method for predicting potential regulatory structures does not

entitle one to examination of any and all potential sequences that result from an algorithm. The contribution that is defined as the technical feature in the instant claims is the ability to predict potential sequences as they might participate in the regulation of gene expression, i.e. micro RNA and corresponding MRE sequences. The positive control for such an algorithm, assuming the algorithm or method of identifying these sequences has any real world use, logically includes previously identified and verified microRNA molecules and their corresponding MRE sequences, which would of course be encompassed by the product by process claims. It is therefore unclear how these previously identified sequences would provide a contribution over the prior art, except to provide validity to the proposed algorithm. Nevertheless, the previously identified sequences encompassed by the composition claims, which would validate the instantly claimed method of identifying sequences, are undoubtedly encompassed by the prior art.

Furthermore, the product by process claim, claim 25, potentially encompasses thousands of sequences, since the claims are not limited to a particular target mRNA, or even limited to a particular genome, etc… And although the individual sequences encompassed by claim 25 are not listed in the alternative, they are still restrictable under Rules 13.1, 13.2 and 13.3 because the expansive genus of compositions encompassed by these claims contain sequences that are structurally and chemically and biologically different and distinct, and each member of the class cannot be substituted one for the other with the expectation that the same intended result would

be achieved or measured (e.g. they would each regulate the expression of different gene sequences with different efficiencies).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 23-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5-4-09.

Claim Objections

Claims 12, 20, 21 are objected to because of the following informalities:

The insertion of commas in claim 12, lines 12-14 is suggested for better understanding of the claim limitations (e.g. inserting a comma after “nucleotides” in line 12, after ”distal region” in line 13, after “nucleotides” in line 14, and after “loop region” of line 14 would perhaps be remedial).

In claim 12, line 3, “sequences” should be singular, not plural, to be grammatically correct.

In claims 20 and 21, line 1, the use of plural for “claims 19” is grammatically incorrect.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, lines 23-27 (step b), the distinction between when there is no loop and when the loop is 0 is unclear. The metes and bounds of a "loop" cannot be determined from the language in this claim. Does a loop exist when there are more sequences bulging out of one of the strands, with respect to the other strand, or does a loop also comprise non-complementary sequences?

In lines 30-32 of claim 12 (step c), it is unclear whether the phrase "including the 5' end of the distal region" pertains to mismatches of 1-4 contiguous nucleotides, or to matches of at least 5 nucleotides to a contiguous nucleotide sequence (e.g. what is the required order of "5 contiguous nucleotide sequences" relative to "1-4 mismatches" with respect to the 5' end of the distal region?).

Appropriate clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of generating a putative microRNA sequence comprising following the steps recited in claim 12, then confirming the

existence of this putative microRNA and its corresponding MRE in the target mRNA using an appropriate blotting technique (e.g. Northern blot), then testing the ability of the putative microRNA to inhibit expression of the corresponding mRNA in an in vitro expression assay, does not reasonably provide enablement for generating a microRNA by only performing the calculations and steps recited in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

.The steps recited in claim 12 provide for candidate sequences that potentially qualify as inhibitory oligonucleotides of mRNA expression, potentially acting in a manner similar to those employed by existing microRNA molecules. But in the absence of confirmatory steps for testing the ability of these candidate molecules to actually inhibit the expression of a corresponding target mRNA, they are putative inhibitory molecules that can potentially inhibit expression of a target gene by any number of mechanisms, such as by blocking transcription or translation, or by acting as microRNA molecules. And in the absence of confirming the actual microRNA molecules' existence and inhibitory function in naturally occurring nucleic acids, the molecules identified using the claimed technique are putative microRNA molecules.

Reciting confirmatory steps as to the purported microRNA molecule's ability to inhibit mRNA expression, and confirming this purported molecule's existence in naturally occurring nucleic acids, would enable a method of identifying candidate

microRNA molecules and their respective MRE sequences on a corresponding mRNA molecule.

Allowable Subject Matter

The steps recited for identifying candidate microRNA and corresponding MRE sequences on a corresponding mRNA molecule appear free of the prior art searched and of record.

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of

a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
8-14-09

/Jane Zara/

Primary Examiner, Art Unit 1635